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21 UNITED STATES DISTRICT COURT
22 SOUTHERN DISTRICT OF CALIFORNIA

23 GEN-PROBE INCORPORATED,

24 Plaintiff,

25 v.

26 VYSIS, INC.,

27 Defendant.

No. 99cv2668 H (AJB)

**MEMORANDUM POINTS AND AUTHORITIES IN
SUPPORT IN SUPPORT OF GEN-PROBE
INCORPORATED'S MOTION FOR LEAVE TO
FILE A SECOND AMENDED COMPLAINT**

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I. INTRODUCTION.

Plaintiff Gen-Probe, Inc. ("Gen-Probe") seeks leave to file a Second Amended Complaint. This motion is brought in good faith, based on facts recently learned or confirmed by Gen-Probe through discovery. Given the substantial amount of time remaining for fact discovery, expert discovery and trial, Defendant Vysis, Inc. ("Vysis") will not be prejudiced by the amendment. Gen-Probe, therefore, respectfully requests that this Court grant leave to amend its complaint.

II. STATEMENT OF FACTS.

Gen-Probe is a local San Diego biotechnology company. Vysis is a successor in interest to Amoco Technology Company and is the owner of United States Patent No. 5,750,338 (the "'338 Patent").

This action concerns the validity and non-infringement of the '338 patent. Through the operative complaint, Gen-Probe seeks a judicial declaration that the '338 patent is not valid, or, in the alternative, a judicial declaration that its NAT test kits for detecting HIV and HCV do not infringe that patent. Declaration of Stephen P. Swinton ("Swinton Decl."), Ex. 1. Gen-Probe also seeks a declaration that Gen-Probe is not obligated to make royalty payments to Vysis pursuant to a license under the '338 patent, and for violations of the California Unfair Business Practices Act, California Business and Professions Code §17200 *et. seq.* *Id.*

A. Procedural History.

Gen-Probe filed its complaint for declaratory relief on December 22, 1999 (Swinton Decl., ¶ 2). Thereafter, on January 26, 2000, Gen-Probe amended the complaint to add its claim for unfair competition. *Id.*, ¶ 2 and Ex. 1.

Following that amendment, and notwithstanding its prior statements to Gen-Probe that Vysis was satisfied with the claims of the '338 patent, Vysis filed a request for reissue of the '338 on the admitted grounds that the patent was "defective" *Id.* at ¶ 5. On the basis of that reissue proceeding, Vysis then moved the Court to stay the action so that it could cure those defects. *Id.* at ¶ 6. This Court denied that motion on April 28, 2000. *Id.* at ¶ 9.

Gen-Probe actively commenced discovery following the Court's denial of Vysis' motion to

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1 stay the case. *Id.* at ¶ 10.¹ Gen-Probe sought documents and interrogatory responses from Vysis
 2 and several third parties and provided its own responses to Vysis' discovery in June 2000. *Id.* at
 3 ¶¶ 13, 14. Many of the inequitable conduct claims set forth in this amended complaint were first
 4 presented to Vysis through that discovery. *Id.*, ¶¶ 11, 13 and Ex. 4.

5 Magistrate Judge Bataglia conducted a Case Management Conference for this matter on
 6 September 13, 2000. Swinton Decl., Ex. 5. The Court then issued a scheduling order on
 7 September 14, 2000. *Id.* That order provides the following relevant dates:

9	Close of fact discovery	April 17, 2001
10	Initial exchange of expert reports	April 23, 2001
11	Close of expert discovery	June 15, 2001
12	Last day to hear pretrial motions	August 6, 2001
13	Pretrial conference	October 8, 2001.

14 *Id.*

15 As indicated above, substantial time remains for discovery and trial of this action.

16 **B. The Proposed Amendment.**

17 By the proposed amendment, Gen-Probe seeks to confirm in its pleading what it
 18 previously substantially disclosed to Vysis in discovery. To begin with, the operative complaint
 19 consists of four counts. Swinton Decl., Ex. 1. In the proposed amended pleading, Gen-Probe has
 20 not altered or amended any of the allegations existing in that amended complaint. Rather, the
 21 proposed complaint adds new matter beginning at page 8.

22 Despite the additional detail set forth in the proposed Second Amended Complaint, the
 23 proposed amendment presents factual allegations for just two new claims for relief for
 24 unenforceability of the '338 patent. *Id.* Count Five asserts various factual allegations establishing
 25 certain acts of Vysis or its predecessors in interest during the prosecution of the '338 patent that

26
 27 ¹ Although the parties initially exchanged written discovery in February and March 2000, they
 28 agreed to stay activity on that discovery during the pendency of the Court's ruling on Vysis' motion to stay. Swinton Decl., ¶¶ 3, 4, 7.

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1 constitute inequitable conduct. *Id.* Consistent with Rule 9(b), Gen-Probe has set forth detailed and
2 specific acts, errors and omissions that substantiate each of the claimed acts of inequitable conduct.
3 *Id.*

4 Count Six asserts a claim for unenforceability due to laches arising from the intentional
5 delays by Vysis and its predecessors-in-interest in the prosecution of the '338 patent. *Id.* The facts
6 supporting this count arise from the repeated abandonment and delays caused by Vysis and its
7 predecessors-in-interest during the twelve-year odyssey of prosecution of the '338 patent. *Id.*

8 **III. GOOD CAUSE EXISTS TO ALLOW GEN-PROBE TO AMEND ITS COMPLAINT.**

9 **A. District Courts Should Grant Leave to Amend With "Extreme Liberality".**

10 Rule 15(a) of the Federal Rules of Civil Procedure provides that "leave to amend
11 shall be given freely when justice requires." FED. R. CIV. P. 15(a). In accordance with the spirit
12 and policy of Rule 15, the Ninth Circuit has routinely directed district courts to grant leave to
13 amend with "extreme liberality." *DCD Programs, LTD. v. Leighton*, 833 F.2d 183, 186 (9th Cir.
14 1987) (citing *United States v. Webb*, 655 F.2d 977, 979 (9th Cir. 1981)).

15 In *DCD Programs*, the plaintiffs asserted claims for damages under the federal and state
16 securities laws. *Id.* at 184. They filed their original complaint in February 1985. *Id.* at 185. In
17 September 1985 they filed a first amended complaint followed by a still further second amended
18 complaint in March 1986. *Id.* In May 1986 they filed a third amended complaint, by which they
19 joined a new defendant for the first time. Then, in a series of hearings in mid-1986, the district
20 court dismissed the third amended complaint against the newly-added defendant and still later
21 denied the plaintiffs' subsequent motion for leave to assert a fourth amended complaint. *Id.*

22 On appeal, the Ninth Circuit found that the district court had abused its discretion in
23 denying plaintiffs' motion for leave to file the fourth amended complaint. In applying the
24 Supreme Court's instructions to grant leave to amend liberally, the court noted four factors that are
25 commonly used to determine the propriety of a motion for leave to amend: (1) bad faith, (2) undue
26 delay, (3) prejudice to the opposing party and (4) futility of amendment. *Id.* at 186. However, as
27 the court noted, these factors are not equal in weight. For example, delay alone is not sufficient to
28 justify a denial of leave to amend. *Id.* Indeed, not only does the opposing party bear the burden of

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1 proof with respect to these four issues, *id.* at 187, but also any effort to claim prejudice requires a
2 substantial showing. See *Morongo Band of Mission Indians v. Rose*, 893 F.2d 1074 (9th Cir.
3 1990).

4 As set forth below, none of these factors supports a denial of Gen-Probe's motion to
5 amend.

6 1. Gen-Probe's Motion For Leave To Amend Is Timely And Made In
7 Good Faith.

8 Under the circumstances of this case, Gen-Probe has timely moved for leave
9 to amend and has acted in good faith. In particular, in light of the application of Rule 9(b) to
10 claims of inequitable conduct, see, e.g., *Chiron Corp. v. Abbott Laboratories*, 156 F.R.D. 219,
11 221-22 (N.D. Cal. 1994), any perceived delay associated with this amendment is entirely
12 attributable to Gen-Probe's good-faith effort to comply with the specificity requirements
13 necessitated by this heightened pleading requirement and is excusable. *Advanced Cardiovascular
Systems, Inc. v. SciMed Life Systems, Inc.*, 989 F. Supp. 1237, 1247 (N.D. Cal. 1997).

14 As set forth in the accompanying declaration of Stephen P. Swinton, based solely on the
15 public record of the prosecution of the '338 patent, Gen-Probe initially believed that certain facts
16 might exist that constitute inequitable conduct. Swinton Decl., ¶ 2. However, mindful of the dual
17 requirements of Rules 9(b) and 11, Gen-Probe determined that it was appropriate to ascertain the
18 facts supporting those suspicions through discovery prior to formal pleading. *Id.* at ¶¶ 2, 3, 4, 16.
19 In the meantime, Gen-Probe nonetheless disclosed in its discovery responses many of the facts that
20 suggested that Vysis had engaged in inequitable conduct. *Id.* at ¶¶ 11, 13 and Ex. 4. Thereafter, in
21 late October 2000, Gen-Probe obtained the deposition testimony of the principal attorney who
22 prosecuted the patent applications that resulted in the issuance of the '338 patent and ultimately
23 gained access in mid-November and early December 2000 to approximately 100,000 pages of
24 documents related in substantial part to the issues raised in the proposed amendment. *Id.* at ¶¶ 16-
25 20 and Ex. 6. That process continues today with Vysis' still further production on
26 January 16, 2001 of nearly 20,000 pages of "overlooked" documents relevant to the claimed
27 conception. *Id.* at ¶ 22.

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1 In view of the obligations imposed upon Gen-Probe under Rules 9(b) and 11, the facts
2 concerning its efforts to discover and amend its pleadings warrant leave to amend. Indeed, in
3 similar situations, district courts have noted that parties seeking to amend a pleading to include a
4 claim that is subject to the particularity requirements of Rule 9(b) of the Federal Rules of Civil
5 Procedure should be afforded substantial temporal leeway to confirm the facts on which that claim
6 is based before seeking leave to amend. *E.g., Advanced Cardiovascular Systems*, 989 F. Supp. at
7 1247.

8 In *Advanced Cardiovascular Systems*, defendant sought to amend its answer to assert a
9 claim for inequitable conduct two years after the action began. *Id.* at 1247. Although the plaintiff
10 argued that the amendment was untimely, the defendant demonstrated that any delay associated it
11 presentation of the amended answer for inequitable conduct was the result of its efforts to confirm
12 through discovery the underlying facts supporting the defense. In allowing the amendment, the
13 district court noted that, particularly in light of the application of Rule 9(b) to the proposed
14 defense, the defendant was entitled to confirm its contemplated factual allegations before seeking
15 leave to amend. *Id.* at 1247.

16 The district court in *Rhone-Poulenc Agro S.A. v. Monsanto Co.*, 73 F. Supp. 2d 537, 538-
17 539 (M.D.N.C. 1999), reached a similar result. There, the district court allowed the defendant to
18 amend its answer to include an inequitable conduct defense, even though the date by which the
19 parties were to have filed amended pleadings had long since passed. *Id.* In that case, the court
20 concluded that the delay in seeking leave to amend was neither purposely dilatory nor in bad faith,
21 reasoning Monsanto was entitled to await the completion of certain discovery that was expected to
22 provide clarifying information before seeking leave to amend. *Id.* To this end, the *Rhone-Poulenc*
23 Court noted that the appropriate inquiry is not whether the interim discovery revealed facts to
24 support the inequitable conduct allegations, but whether it was reasonable for the party seeking to
25 amend to expect to obtain clarifying information as a result of that discovery. *Id.*

26 As noted above, Gen-Probe earlier suspected that Vysis may have engaged in inequitable
27 conduct during the prosecution of the myriad of patent applications that matured into the '338
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1 patent.² But rather than seeking leave to file a pleading containing potentially insufficient or
2 unsubstantiated allegations of inequitable conduct at that time, Gen-Probe chose, in good faith, to
3 await the completion of certain discovery it believed necessary to confirm its suspicions. Swinton
4 Decl., ¶¶ 2, 3, 4, 16. To confirm the factual basis for its inequitable conduct charges, Gen-Probe
5 propounded document requests and subpoenas and took the Rule 30(b)(6) deposition of Vysis and
6 Amoco on the prosecution of the patent applications that led to the issuance of the '338 patent. *Id.*
7 at ¶¶ 3, 4, 16. During that deposition, Gen-Probe gathered additional facts to support its
8 inequitable conduct allegations. *Id.* at ¶ 18.

9 Gen-Probe did not immediately move for leave to amend following the October 27th
10 deposition of Vysis and Amoco because Vysis had not yet produced the vast majority of the
11 documents responsive to Gen-Probe's document requests. *Id.* at ¶ 19. Gen-Probe believed that
12 these documents would contain additional information necessary to confirm the factual basis for
13 the inequitable conduct allegations. *Id.* Additionally, at that time, Gen-Probe still awaited the
14 production of documents responsive to certain subpoenas that Gen-Probe had propounded to third
15 parties believed to possess documents pertaining to the prosecution of the relevant patent
16 applications. *Id.* Gen-Probe believed that the documents responsive to the subpoenas were also
17 necessary to validate its inequitable conduct theories. *Id.*

18 During mid-November and early December 2000, Vysis produced approximately 100,000
19 pages of documents responsive to Gen-Probe's document requests. Swinton Decl., ¶ 20. Gen-
20 Probe completed a preliminary review of these documents in early January 2001. *Id.* at ¶ 21. On
21 January 16, 2001, Vysis produced another 8 bankers' boxes of responsive documents, which boxes
22 contain nearly 20,000 pages of additional documents. *Id.* at ¶ 22.

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24
25 ² Gen-Probe first alluded to its inequitable conduct theories in its Memorandum Of Points And
26 Authorities Of Gen-Probe Incorporated In Response To Vysis' Motion: (1) For A Stay Of
27 Proceedings And, Alternatively, (2) To Dismiss Count Four Under Federal Rule Of Civil
28 Procedure 12(b)(6). Swinton Decl., ¶ 8 and Ex. 3. Thereafter, on May 17, 2000, Gen-Probe Vysis
propounded discovery seeking the basis of the inequitable conduct allegations to which Gen-Probe
referred in those papers. *Id.* at ¶ 11. Gen-Probe provided a response to that discovery on
June 20, 2000. *Id.* at ¶ 13 and Ex. 2.

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1 In short, Gen-Probe's motion for leave to amend is timely and made in good faith. Rather
2 than rush to file speculative or unsubstantiated claims of inequitable conduct, Gen-Probe exercised
3 good faith and waited until it had gathered and confirmed facts to support its allegations that Vysis
4 had engaged in inequitable conduct in connection with the prosecution of the various patent
5 applications that led to the '338 patent. Gen-Probe should not be criticized for delay or bad faith.

6 **2. Granting Gen-Probe Leave To Amend Will Not Prejudice Vysis.**

7 The further factor of prejudice also does not apply in this instance. In light
8 of the substantial time remaining before the close of fact and expert discovery, Vysis will not be
9 unduly prejudiced by the proposed amendment.

10 To begin with, as noted above, the Ninth Circuit has directed that any prejudice sufficient
11 to deny amendment must be substantial. *DCD Programs*, 833 F.2d at 186. In this case, however,
12 any anticipated argument of prejudice to Vysis cannot rise to that level. In truth, because *all* the
13 evidence concerning Gen-Probe's proposed claims of inequitable conduct and laches is solely
14 within the possession of Vysis already, there exists significant question as to whether any
15 prejudice, whatsoever, will arise.

16 In *Rhone-Poulenc*, for example, the court held the plaintiff would suffer no prejudice if the
17 defendant was allowed to amend its answer to include an inequitable conduct defense, even though
18 the discovery cut-off passed weeks *before* the motion for leave to amend was filed. 73 F. Supp. 2d
19 at 539. The *Rhone-Poulenc* court reasoned that because the inequitable conduct allegations related
20 to the prosecution of the patent-in-suit and because the party seeking to amend had provided an
21 analysis of its inequitable conduct defense, little, if any, additional discovery would be necessary.
22 *Id.*

23 Consistent with the absence of substantial prejudice in the *Rhone-Poulenc* case, Vysis
24 cannot establish prejudice here. To begin with, the factual underpinning for inequitable conduct
25 allegations contained in Gen-Probe's proposed Second Amended Complaint are the acts of Vysis
26 and its predecessors-in-interest. Vysis has access to all the documentary evidence relevant to the
27 prosecution of the various patent applications that led to the '338 patent. In addition, the attorney
28 responsible for prosecuting the relevant patent applications is a current Vysis employee. Swinton

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Decl., Ex. 6. Further, as was the case in *Rhone-Poulenc*, Gen-Probe has concurrently provided Vysis with a detailed analysis of its inequitable conduct allegations by way of the amended pleading and discovery.

Finally, the likelihood for prejudice is even less, here, than it was in *Rhone-Poulenc*, because, here, the discovery cut-off has not yet passed. Given that discovery does not close until April 17, 2001 and that Vysis has yet to conduct a single deposition, *id.* at ¶ 24, there is more than sufficient time for Vysis to conduct discovery into and respond fully to these amendments. In sum, Vysis will not suffer any prejudice if Gen-Probe is granted leave to amend.

3. Gen-Probe's proposed amendment is not futile.

The final factor of "futility" also supports Gen-Probe's proposed amendments. An amendment is "futile" only if it merely reasserts a claim on which the court previously ruled, fails to state a legal theory, or could not withstand a motion to dismiss. *Bowery v. Jones*, 978 F.2d 1004, 1008 (7th Cir. 1982); *see, e.g., Doe v. United States*, 58 F.3d 494, 497 (9th Cir. 1995). The proposed pleading states *prima facie* claims of unenforceability due to inequitable conduct and laches, neither of which have yet been presented to this Court.

As to its claim for inequitable conduct, Gen-Probe has plead each of the essential elements of inequitable conduct: "(1) prior art or information that is material; (2) knowledge chargeable to applicant of that prior art or information and of its materiality; and (3) failure of the applicant to disclose the art or information resulting from an intent to mislead the PTO." *FMC Co. v. Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1997). Each of Gen-Probe's identified acts of inequitable conduct set forth these essential elements.

Gen-Probe's allegations also satisfy the particularity requirements of Rule 9(b). In particular, Gen-Probe has identified "the circumstances constituting fraud . . . so that the defendant can prepare an adequate answer from its allegations." *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Throughout its unenforceability count, Gen-Probe describes each of Vysis' misrepresentations to the Patent Office by specifying dates on which they occurred, the content thereof, and how those misrepresentations were false and misleading.

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With respect to Gen-Probe's claim for unenforceability due to laches in the prosecution of the '338 patent, Gen-Probe has modeled that claim in light of arguments currently before the Court of Appeals for the Federal Circuit in the matter entitled *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, Limited Partnership*, 2000 WL 1300430 (Fed. Civ. Sept. 1, 2000) (Notice of Lodgment, Ex. 1). In that case, the defendant contends that Lemelson unduly delayed the prosecution of the patents-in-suit by abusing the continuation application process. *Id.* Although the district court in that matter dismissed that defense of "prosecution laches" under Rule 12(b)(6), the district court certified its order, finding that the claim involved a controlling question of law as to which there was a substantial ground for difference of opinion. *Id.* at *2. The Federal Circuit accepted the matter for interlocutory review. *Id.* The district court's certification of the legitimacy of the issue and the Federal Circuit's acceptance of that matter for rare, interlocutory review suggests that the defense is viable and applicable to the stated facts surrounding Vysis extraordinary 12-year odyssey of self-imposed and manipulated delays in the Patent Office.

IV. CONCLUSION.

For the foregoing reasons, Gen-Probe respectfully requests that the Court grant its motion for leave to file its Second Amended Complaint.

Dated: January 19, 2001

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